

**ENTERED**

January 31, 2023

Nathan Ochsner, Clerk

**In the United States District Court  
for the Southern District of Texas**

GALVESTON DIVISION

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No. 3:21-cv-90

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SARAH PALMQUIST, *ET AL.*, *PLAINTIFFS*,

v.

THE HAIN CELESTIAL GROUP, INC., *DEFENDANT*.

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**MEMORANDUM OPINION AND ORDER**

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JEFFREY VINCENT BROWN, *UNITED STATES DISTRICT JUDGE*:

The defendant, Hain Celestial Group, Inc., has moved for summary judgment on all claims in the plaintiffs' second amended complaint. Dkt. 54. The court grants in part and denies in part.

The plaintiffs, Dr. Sarah and Mr. Grant Palmquist, have moved for summary judgment on Hain's fourth defense. Dkt. 52. The court denies.

**I. BACKGROUND**

In this products-liability action, the Palmquists seek damages from Hain, a baby-food manufacturer, for their son Ethan's tragic physical and mental decline when he was about 30 months old. Dkts. 6 ¶¶ 3, 29.

After a healthy and uneventful pregnancy, Sarah Palmquist gave birth to Ethan in September 2014. *Id.* at ¶ 29. For his first couple of years, Ethan met or exceeded developmental milestones. *Id.*; *see also* Dkt. 50-42 ¶ 147. But when Ethan was about thirty months old, his “social, language, and behavior” skills rapidly regressed. Dkt. 50-42 ¶ 147. Until he was about three years old, Ethan almost exclusively consumed Hain’s Earth’s Best products. Dkt. 69 at 7 (citing Dkts. 64-5 at 3; 69-6 at 3–11).

Concerned that Ethan’s sudden decline pointed to a brain injury, the Palmquists employed numerous physicians and specialists to identify a cause and an appropriate treatment plan. Dkt. 69 at 6. The various tests revealed that Ethan suffered from several physical and mental disorders. Ethan’s physical ailments include seizure disorder, chronic diarrhea, epileptiform disorder (excessive and abnormal brain activity), hypotonia (abnormally decreased muscle tone), unspecified encephalopathy,<sup>1</sup> neurological abnormality, and mitochondrial<sup>2</sup> dysfunction. Dkts. 64 at 7–8; 50-28 at 4.

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<sup>1</sup> Encephalopathy is a broad term encompassing “any disease of the brain that alters brain function or structure.” *Encephalopathy*, Nat’l Inst. of Neurological Disorders & Stroke, <https://www.ninds.nih.gov/health-information/disorders/encephalopathy> (last reviewed Jan. 20, 2023).

<sup>2</sup> “Mitochondrial diseases are caused by defects in mitochondria, which are energy factories found inside almost all the cells in the body . . . . [M]uscular and neurological problems are common features of mitochondrial disease.”

Ethan's mental diagnoses range from intellectual disability to anxiety and aggression. Dkts. 64 at 8; 50-28 at 4. Some physicians lumped most, if not all, of Ethan's symptoms into blanket diagnoses of autism spectrum disorder or major neurocognitive disorder. *See, e.g.*, Dkts. 53-5 at 17; 50-42 at 46. Some physicians also diagnosed Ethan with heavy-metal poisoning. Dkts. 69 at 6; 50-28 at 16; *see also* Dkt. 65 at 6–9 (surveying Ethan's heavy-metal tests). Consuming heavy metals is widely known to lead to cognitive impairment, severe illness, and—at high levels—death. *See* Dkt. 64 at 35–37 (collecting citations).

The Hain products Ethan consumed may have had harmful toxic-metal concentrations. From 2014 to 2019, Hain tested some ingredients in its baby foods for toxic metals but did not test the end products. Dkt. 69 at 8 (citing Dkt. 64-18 at 232:2–14, and Dkt. 64-6 at 143:3–23). In 2016, the Food and Drug Administration (FDA) published draft guidance recommending that infant-rice-cereal producers limit end-product inorganic-arsenic levels to

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*Mitochondrial Myopathy Fact Sheet*, Nat'l Inst. of Neurological Disorders & Stroke, <https://www.ninds.nih.gov/mitochondrial-myopathy-fact-sheet> (last reviewed July 25, 2022).

100 parts per billion (ppb).<sup>3</sup> *Id.*; Dkt. 69-10 at 7. Before late 2016, Hain set its ingredient-heavy-metal limit at 200 ppb. Dkt. 69 at 8. When a particular ingredient exceeded that limit, Hain would perform “theoretical calculations” to estimate the finished product’s heavy-metal content. *Id.* at 9. Hain used these theoretical calculations to justify approving vitamin pre-mix batches with 223 ppb arsenic and 352 ppb lead. Dkt. 64-17, Milewski Dep. 112:23–115:8; *see also* Dkt. 69 at 10 (summarizing internal- and external-audit results of Hain’s Earth’s Best products performed between 2018 and 2019, showing inorganic-arsenic levels exceeding 100 or 200 ppb and lead levels exceeding 300 ppb). A 2021 congressional report revealed other troubling findings: Hain’s Earth’s Best products contained up to 129 ppb inorganic arsenic; some of Hain’s ingredients contained as much as 352 ppb lead; and Hain did not test for mercury. Dkt. 69 at 10; *see also* Dkts. 101 at 4, 41; 69-13 at 9.

Hain has tried to reduce the heavy-metal concentration in its products. In 2019, Hain stopped using the vitamin pre-mix ingredient, switched to a lower-arsenic-content rice for its infant cereal, and started final-product

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<sup>3</sup> The FDA formally published the nonbinding recommendations in 2020. *See* Dkt. 69 at 9 (citing FDA, Inorganic Arsenic in Rice Cereals for Infants: Action Level Guidance for Industry (Aug. 2020), <https://tinyurl.com/2p8p6tj3>).

testing. Dkt. 69 at 12. These particular changes occurred too late to affect the products that Ethan consumed before developing his condition. *Id.*

The Palmquists originally sued Hain and Whole Foods Market Rocky Mountain/Southwest, L.P., alleging strict-products-liability and negligence claims and seeking damages for Ethan’s injuries. Dkts. 6 ¶¶ 7–8, 40–68. The court subsequently found that the Palmquists improperly joined Whole Foods and dismissed their claims against it. Dkt. 29. Both parties moved to exclude (Dkts. 50, 51, 53, 61) and to strike (Dkts. 49, 68) causation- and genetics-related expert testimony, which the court denied. Dkt. 99. Hain has asked for summary judgment on all claims, Dkt. 54, and the Palmquists have asked for summary judgment on Hain’s fourth defense, Dkt. 52.

## **II. LEGAL STANDARD**

Summary judgment is proper when “there is no genuine dispute as to any material fact and the movant is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(a). The court must view the evidence in the light most favorable to the nonmovant. *Coleman v. Hous. Indep. Sch. Dist.*, 113 F.3d 528, 533 (5th Cir. 1997). For each cause of action moved on, the movant must set forth those elements for which it contends no genuine dispute of material fact exists. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The burden then shifts to the nonmovant to offer specific facts showing a genuine dispute

for trial. *See* Fed. R. Civ. P. 56(c); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986). “A dispute about a material fact is ‘genuine’ if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Bodenheimer v. PPG Indus., Inc.*, 5 F.3d 955, 956 (5th Cir. 1993).

The court “may not make credibility determinations or weigh the evidence” in ruling on a summary-judgment motion. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000). But when the nonmoving party has failed “to address or respond to a fact raised by the moving party and supported by evidence,” then the fact is undisputed. *Broad. Music, Inc. v. Bentley*, No. SA-16-CV-394-XR, 2017 WL 782932, at \*2 (W.D. Tex. Feb. 28, 2017) (citing Fed. R. Civ. P. 56(e)(2)). “Such undisputed facts may form the basis for summary judgment.” *Id.*

### **III. ANALYSIS**

Hain moves for summary judgment on all claims. Dkt. 54. The Palmquists ask for summary judgment on Hain’s fourth defense. Dkt. 52.

Texas law applies in this diversity action. *James v. Woods*, 899 F.3d 404, 408 (5th Cir. 2018) (citing *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938)). “Under Texas law, a plaintiff can recover in a products-liability case under three theories: strict liability, negligence, and breach of warranty.”

*Herbst v. Deere & Co.*, No. 3:21-CV-44, 2021 WL 5567379, at \*1 (S.D. Tex. Nov. 29, 2021) (quoting *Romo v. Ford Motor Co.*, 798 F. Supp. 2d 798, 805 (S.D. Tex. 2011)).

The Palmquists allege strict liability and negligence. Dkt. 6 ¶¶ 40–56. Strict-liability cases concern whether a product was defective, while negligence cases concern whether a manufacturer acted without ordinary care. *Williams v. Apple Inc.*, No. CV H-19-782, 2019 WL 2057960, at \*3 (S.D. Tex. May 9, 2019) (citing *Syrie v. Knoll Int’l*, 748 F.2d 304, 307 (5th Cir. 1984)).

### **A. Hain’s Motion for Summary Judgment**

Hain asks for summary judgment on the following grounds: (1) the Palmquists lack sufficient expert testimony to show causation, (2) Hain is entitled to a nonliability presumption on the marketing-defect claim, (3) the Palmquists do not offer a safer alternative design to support the design-defect claim, (4) the Palmquists do not identify the specific-product deviation necessary for a manufacturing defect, and (5) the Palmquists’ negligence claims must fail with their products-liability claims. Dkt. 54 at 7–30.

#### **1. Causation**

Product-liability and negligence claims “both require proof of

causation.” *Meador v. Apple, Inc.*, 911 F.3d 260, 264 (5th Cir. 2018). Negligence claims require “proximate cause,” consisting “of both cause in fact and foreseeability.” *Id.* (quoting *Union Pump Co. v. Allbritton*, 898 S.W.2d 773, 775 (Tex. 1995), *abrogated on other grounds by Ford Motor Co. v. Ledesma*, 242 S.W.3d 32 (Tex. 2007)). Product-liability claims require a “producing cause” or “cause in fact” but not foreseeability. *Meador*, 911 F.3d at 264. “Cause in fact means that the defendant’s act or omission was a substantial factor in bringing about the injury which would not otherwise have occurred.” *Allbritton*, 898 S.W.2d at 775.

Cause in fact has two levels: general and specific. *Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 377 (5th Cir. 2010). “General causation is whether a substance is capable of causing a particular injury or condition in the general population,” and “specific causation is whether a substance caused a particular individual’s injury.” *Id.* at 378 (quoting *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 351 (5th Cir. 2007)).

The plaintiff must present “competent evidence” showing “[t]he causal nexus between the event sued upon and the plaintiff’s injuries.” *Morgan v. Compugraphic Corp.*, 675 S.W.2d 729, 732 (Tex. 1984). In Texas, “[t]he general rule has long been that expert testimony is necessary to establish causation as to medical conditions outside the common knowledge and



experience of jurors.” *Guevara v. Ferrer*, 247 S.W.3d 662, 665 (Tex. 2007) (collecting cases).

The parties disagree about how to characterize Ethan’s injury and—correspondingly—how to frame the Palmquists’ causation burden. Hain asks for summary judgment on all claims because the Palmquists’ experts did not offer reliable testimony showing that heavy-metal poisoning causes *autism*. Dkt. 54 at 8–13. But the court cannot grant Hain summary judgment on an issue that the Palmquists did not raise. The Palmquists never mention autism in their complaint. *See generally* Dkt. 6. Instead, the Palmquists seek to show that heavy-metal exposure causes heavy-metal poisoning and that Ethan’s consumption of heavy metals in Hain’s products caused his heavy-metal poisoning and resultant cognitive decline.<sup>4</sup> Dkt. 69 at 14–20; *see also* Dkt. 64 at 27–28.

Hain’s causation arguments do not address the Palmquists’ causation theory as pleaded. Accordingly, the court denies Hain’s request for summary judgment on all claims for failure to show causation.

## **2. Strict Liability**

The Palmquists’ strict-liability claims arise from Hain’s alleged

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<sup>4</sup> The Palmquists argue, and Hain does not generally dispute, that exposure to heavy metals will, at some point, cause cognitive decline. Dkt. 64 at 37–39.

marketing, design, and manufacturing defects. The court considers whether summary judgment for Hain is warranted under any of the theories in turn.

### **a. Marketing Defect**

The Palmquists allege that Hain’s failure to warn consumers about the heavy-metal content in its products constituted a marketing defect. Dkt. 6 ¶¶ 53–54. Hain does not contest that its failure to warn may have made its products unreasonably safe; instead, Hain asks for summary judgment on this claim because Texas law entitles it to a nonliability presumption. Dkt. 74 at 11–13; *see also* Tex. Civ. Prac. & Rem. § 82.008.

“[F]ailure to provide adequate warnings or instructions” may render a product “unreasonably dangerous.” *Ranger Conveying & Supply Co. v. Davis*, 254 S.W.3d 471, 480 (Tex. App.—Houston [1st Dist.] 2007, pet. denied); *Am. Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 426 (Tex. 1997). A marketing-defect claim’s elements are

- (1) a risk of harm that is inherent in the product or that may arise from its intended or reasonably anticipated use of the product;
- (2) the supplier of the product knows or reasonably should foresee the risk of harm at the time the product is marketed;
- (3) the product has a marketing defect [(i.e., it lacks adequate warnings or instructions)];
- (4) the lack of warnings or instructions renders the product unreasonably dangerous to the ultimate user or consumer; and
- (5) the failure to warn or instruct causes the user’s injury.

*Moreno v. Allison Med., Inc.*, No. 3:20-CV-00300, 2022 WL 3702061, at \*6

(S.D. Tex. Aug. 9, 2022), *report and recommendation adopted*, No. 3:20-CV-00300, 2022 WL 3703858 (S.D. Tex. Aug. 26, 2022) (citing *Ranger*, 254 S.W.3d at 480, and *Goodyear Tire & Rubber Co. v. Rios*, 143 S.W.3d 107, 116 (Tex. App.—San Antonio 2004, pet. denied)).

A manufacturer is entitled to a nonliability presumption, however, if it can show “that (1) the product complied with mandatory federal safety standards or regulations, (2) the standards or regulations were applicable to the product at the time of manufacture, and (3) the standards or regulations governed the product risk that allegedly caused the harm.” *Kia Motors Corp. v. Ruiz*, 432 S.W.3d 865, 870 (Tex. 2014); *see also* Tex. Civ. Prac. & Rem. Code § 82.008. The claimant may rebut this presumption if (1) “the mandatory federal safety standards or regulations applicable to the product were inadequate to protect the public from unreasonable risks of injury or damage” or (2) the manufacturer withheld or misrepresented information relevant to the government’s determination that the regulations were adequate. Tex. Civ. Prac. & Rem. Code § 82.008(b).

The parties disagree on whether the nonliability presumption protects Hain from marketing-defect liability as a matter of law. According to Hain, the presumption applies because Hain complied with the FDA’s “labeling requirements,” including

- 21 C.F.R. § 101.4 (outlining the requirements to include ingredients on labels);
- 21 C.F.R. § 101.100 (exempting certain food products and ingredients from ingredient-disclosure requirements);
- 21 C.F.R. § 101.17 (outlining situations when manufacturers must include safety warnings on their product labels); and
- The Food Allergen Labeling and Consumer Protection Act of 2004 (requiring manufacturers to have warnings for specific allergens deemed most likely to cause severe injury).

Dkt. 54 at 14.

The Palmquists do not dispute that these regulations generally apply to Hain’s products or that they existed when Hain manufactured the food Ethan consumed. *See* Dkt. 69 at 28–30. But they argue that the regulations Hain relies upon do not govern the product risk that caused Ethan’s injury. *Id.* at 30.

The plain text of § 82.008 requires that the regulation at issue govern the “*risk*” that caused the harm, “not a particular product *defect*.” *Kia*, 432 S.W.3d at 873 (citing *Wright v. Ford Motor Co.*, 508 F.3d 263, 270 (5th Cir. 2007), and Tex. Civ. Prac. & Rem. Code § 82.008(a)). Though the product defect is “not immaterial to the analysis,” the defect’s scope does not define whether the presumption applies; instead, courts evaluating whether the nonliability presumption applies “closely examine both [(1)] the product risk arising from an alleged design defect and [(2)] the parameters of the

regulation at issue.” *Kia*, 432 S.W.3d at 873–74.

Hain characterizes the product risk two different ways. First, in its motion for summary judgment, Hain identifies the risk as “the failure to disclose a particular component of a food product.” Dkt. 74 at 11. In its reply, Hain reframes the risk as “injury due to a failure to disclose certain ingredients.” Dkt. 74 at 12. The Palmquists characterize the product risk as “consumption of harmful levels of toxic metals.” Dkt. 69 at 29

Hain’s most persuasive product-risk characterization is “injury due to a failure to disclose certain ingredients.” Dkt. 74 at 12. That said, Hain’s argument that the heavy metals in its products are not necessarily “ingredients” but mere “additives” undercuts its product-risk characterization. *See* Dkt. 54 at 15. Moreover, the product risk must *arise* from the alleged product defect. *Kia*, 432 S.W.3d at 873–74. The Palmquists do not argue that Hain should have warned of the presence of particularly problematic ingredients (like the vitamin pre-mix); rather, they claim that the product defect is Hain’s failure to warn of the risk of consuming products “containing high levels of heavy toxic metals.” *See* Dkt. 6 ¶ 53. Thus, the Palmquists properly frame the risk arising from the product defect: consuming harmful levels of toxic metals. *See* Dkt. 69 at 29. Because Ethan’s alleged injury is heavy-metal poisoning, the court adopts the Palmquists’

product-risk characterization.

The court next considers the parameters of the regulations that Hain claims govern the product risk at issue. As explained below, these regulations do not protect Hain from liability as a matter of law.

**i. 21 C.F.R. § 101.17**

Hain argues that 21 C.F.R. § 101.17 “govern[s] instances when a manufacturer must warn consumers of a particular hazard or ingredient” in a food product. Dkt. 54 at 15. The Palmquists respond that 21 C.F.R. § 101.17(e) covers the risk of *accidentally* ingesting products not meant for children. Dkt. 69 at 30. Although this is true of § 101.17(e) specifically, other parts of the regulation apply to products potentially intended for children. *See, e.g.*, 21 C.F.R. § 101.17(g) (governing disclosures on certain juices and purees). Still, it does not go so far as to regulate the risk of consuming toxins or heavy metals. *See generally* 21 C.F.R. § 101.17. Therefore, it does not govern the product risk that allegedly caused Ethan’s injury.

**ii. The Food Allergen Labeling and Consumer Protection Act (FALCPA)**

Hain also cites to the FDLCPA, which requires food manufacturers to “warn consumers when a product has one of eight major allergens that pose severe safety risks to consumers with allergies.” Dkt. 54 at 15. Hain does not contend, however, that any of the heavy metals identified in its baby-food

products are FDLCPA-governed allergens. *See id.* at 14. Therefore, the FDLCPA also does not govern the product risk here.

**iii. 21 C.F.R. § 101.4 and 21 C.F.R. § 101.100**

Finally, Hain points to 21 C.F.R. § 101.4 and § 101.100. *Id.* As explained in more detail below, these regulations may govern the product risk in this case. But even if they do, a genuine issue of material fact remains as to whether Hain complied with the regulations. If Hain did not comply, it cannot avail itself of the nonliability presumption.

These provisions apply in tandem to outline the obligation to include ingredients on food-product labels and to provide for certain exemptions. *See* 21 C.F.R. § 101.4(a)(1). Section 101.100 exempts “incidental additives” from a manufacturer’s labeling obligations when those additives “are present in a food at *insignificant* levels and do not have any technical or functional effect in that food.” *Id.* § 101.100(a)(3) (emphasis added). “Incidental additives” include both (1) “[s]ubstances that have no technical or functional effect but are present in a food [because they were] incorporated into the food as an ingredient of another food, in which the substance did have a functional or technical effect” and (2) “[s]ubstances migrating to food from equipment or packaging or otherwise affecting food that are not food additives.” *Id.* § 101.100(a)(3)(i), (iii).

Hain argues that these regulations govern the risk of heavy-metal consumption because heavy metals are “incidental additives” that migrate to food through the environment where ingredients grow. *See* Dkt. 54 at 15 (citing 21 C.F.R. § 101.100(a)(3)(iii)). The Palmquists argue that even if this regulation governs the product risk of consuming harmful levels of heavy metals, Hain is not entitled to protection because the heavy-metal levels in Hain’s products were not “*insignificant*.” *See* Dkt. 69 at 30 (quoting 21 C.F.R. § 101.100(a)(3)).

The Palmquists point to multiple metrics that support their argument that the heavy-metal levels in Hain’s products were not “insignificant”:

- (1) FDA draft guidance from 2016 recommending that producers of infant-rice cereals limit inorganic-arsenic levels to 100 ppb. Dkts. 69 at 9; 69-10 at 7.
- (2) Hain’s pre-2016 product heavy-metal limits of 200 ppb arsenic, lead, and cadmium. Dkt. 69 at 8.
- (3) EPA-, WHO-, and FDA-recommended heavy-metal levels in drinking water, EU limits in infant formula, and the Consumer Reports recommended heavy-metal levels in baby food. *See* Dkts. 50-1 at 25–28; 50-7.

Measuring against these metrics, the court is not convinced that the heavy-metal levels in Hain’s products and ingredients were “insignificant.”

In sum, there is a genuine issue of material fact as to whether Hain “complied” with 21 C.F.R. § 101.4 and § 101.100. Because compliance with



the governing regulations is necessary to trigger the nonliability presumption, Hain is not entitled to the presumption.

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Therefore, it is not clear as a matter of law that Hain is entitled to the nonliability presumption on the Palmquists' marketing-defect claim.<sup>5</sup> Because Hain does not otherwise challenge the claim, it survives summary judgment.

### **b. Design Defect**

The court grants Hain summary judgment on the Palmquists' design-defect claim because the Palmquists do not present evidence creating a genuine issue of material fact as to the feasibility of their proposed safer alternative design.

Under Texas law, plaintiffs alleging a design defect must show that “(1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury for which the plaintiff seeks recovery.”

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<sup>5</sup> Even if the regulations Hain relies upon encompass all potential labeling requirements, the court would still deny summary judgment. The presumption still would not apply as a matter of law because, taking the evidence in a light most favorable to the Palmquists, it is unclear that the regulations are “[a]dequate to protect the public from unreasonable risks of injury or damage.” *See* Dkt. 69 at 30–32; *see also* Dkt. 50-1 at 25–28.

*Emerson Elec. Co. v. Johnson*, 627 S.W.3d 197, 203 (Tex. 2021) (quoting *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009)); see Tex. Civ. Prac. & Rem. Code § 82.005. Hain argues that the Palmquists’ design-defect claim fails on the second element: proof of a safer alternative design. Dkt. 54 at 18.

A “safer alternative design” exists if the plaintiffs show a reasonable probability that the proposed design (1) would “significantly reduce the risk” of the plaintiff’s injury “without impairing the product’s utility” and (2) was “economically and technologically feasible” when the product was manufactured. See Tex. Civ. Prac. & Rem. Code § 82.005. Many courts applying Texas law require expert testimony to show a safer alternative design. *Norman v. Grove Cranes U.S., L.L.C.*, 750 F. App’x 269, 273 (5th Cir. 2018) (collecting cases). At the least, the Palmquists must make “[m]ore than a ‘bald assertion’ that an alternative design” exists. *Hodges v. Mack Trucks Inc.*, 474 F.3d 188, 197 (5th Cir. 2006) (citing *GMC v. Sanchez*, 997 S.W.2d 584, 591–92 (Tex. 1999)).

To the extent the Palmquists pleaded a safer alternative design, Hain argues that they have not established the design’s technological and economic feasibility. Dkt. 54 at 20–21 (noting that heavy metals naturally exist in the environment and that there are costs and relative nutritional

disadvantages with decreasing the heavy-metal concentration in foods); *see also* Dkt. 74 at 10–11. To show feasibility, the Palmquists rely solely on the testimony of Hain’s corporate representative, Lauren Breaux. *Id.* at 26–27.

The Palmquists argue that they do not need expert evidence on feasibility because Breaux testified that safer-alternative-design changes were economically and technologically feasible as early as 2014—when Hain manufactured the products Ethan consumed. *Id.* at 26 (citing Dkt. 64-18, Breaux Dep. 106:15–112:19). But Breaux’s testimony about feasibility is too speculative and uncertain to show feasibility. Breaux was not involved with Hain’s Earth’s Best line in 2014. *See* Dkt. 64-18, 112:12–19, 182:8–18, 237:17–20. And her testimony, to the extent it is not speculative, is inconclusive as to feasibility. For instance, when discussing the feasibility of switching from brown rice to white rice, Breaux notes Hain’s struggle to find a white-rice supplier when it made the switch in 2016 and points out that Hain used brown rice before then because of its relatively higher nutritional value. *Id.* at 236:6–23. Breaux’s testimony is too speculative and ambivalent to satisfy the Palmquists’ burden to make more than a “bald assertion” that a safer alternative design existed in 2014.

Thus, even taking the facts in a light most favorable to the Palmquists, their design-defect claim fails as a matter of law because they did not

establish the feasibility of their proposed safer alternative design.

### **c. Manufacturing Defect**

Under Texas law, a manufacturing defect exists “when a product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous.” *Casey v. Toyota Motor Eng’g & Mfg. N. Am., Inc.*, 770 F.3d 322, 326 (5th Cir. 2014) (citing *Cooper Tire & Rubber Co. v. Mendez*, 204 S.W.3d 797, 800 (Tex. 2006)). “A plaintiff ‘must prove that the product was defective when it left the hands of the manufacturer and that the defect was a producing cause of the plaintiff’s injuries.’” *Norman v. Bodum USA, Inc.*, 44 F.4th 270, 272 (5th Cir. 2022) (quoting *Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 600 (Tex. 2004)).

To distinguish a manufacturing-defect claim from a design-defect claim, Texas courts require plaintiffs to “allege a specific deviation from the product’s intended design that allegedly caused the injury.” *Norman*, 44 F.4th at 272 (citing *Casey*, 770 F.3d at 326, and *Ridgway*, 135 S.W.3d at 600). This deviation requirement is essential; as the *Norman* court explained

[i]f there is no deviation from the defendant’s intended design, then the design itself is the alleged problem. In that situation, plaintiffs must bring a design defect claim, which requires proof

of an additional safer alternative design element. In a manufacturing defect case, by contrast, the plaintiff must present proof of a manufacturer's intended design, from which the actual product in question deviated as a result of a defect in the manufacturing process.

*Norman*, 44 F.4th at 272 (internal quotations and citations omitted) (collecting Texas cases).

Hain first argues that the Palmquists' claim must fail because they "have failed to identify a specific deviation from the product design that caused [Ethan's] injuries." Dkt. 54 at 22. Specifically, Hain argues that high heavy-metal levels in baby food cannot be a manufacturing defect because heavy metals are ubiquitous in the environment and naturally occur in the ingredients it uses. *Id.* at 22–23. Yet Hain's products may deviate from its heavy-metal-concentration specifications even if eliminating heavy metals is impossible. In fact, the Palmquists presented evidence showing that (1) Hain knew the heavy-metal concentrations in some of its ingredients exceeded its concentration specifications and (2) Hain's "theoretical" end-product calculations sometimes underestimated the actual toxic-metal concentration of products incorporating those ingredients. *See generally* Dkt. 69 at 21–22; *see also* Dkt. 64-17, Milewski Dep. 269:19–270:13; 101 at 39.

Hain also contends that the Palmquists' manufacturing-defect claim failed "to demonstrate that the products [Ethan] allegedly consumed were

different than other similar products in the Earth's Best product line.” Dkt. 54 at 23. Indeed, Hain argues that the Palmquists’ manufacturing-defect claim cannot rest on a claim that Hain’s entire product line was defective. *Id.* (citing *Cofresi v. Medtronic, Inc.*, 450 Supp. 3d 759, 767 (W.D. Tex. 2020)). As the Palmquists point out, however, the law “do[es] not provide a loophole for manufacturers to avoid liability simply because their defects were flagrant or widespread.” Dkt. 69 at 24. Under Texas law, “a tolerated defect—even one that is tolerated *and* ubiquitous throughout an entire industry—is still a defect if it is unintended.” *Norman*, 44 F.4th at 274 (citing *Grinnell*, 951 S.W.2d at 433–34).

In *Norman*, the plaintiffs brought a manufacturing-defect claim against the manufacturer of a French-press coffee maker. 44 F.4th at 271. The alleged defect that caused the press to shatter during ordinary use was “an end-piece of the [p]ress’s metal coil that, instead of being tucked inwards, protruded outwards beyond the protective mesh.” *Id.* at 273. Because the manufacturer advertised and sold other coil assemblies that protruded, the district court found that it could not infer that the protruding coil was a manufacturing defect. *Id.* at 274. In reversing the district court, the Fifth Circuit noted that the manufacturer’s advertising of other products with protruding coils could suggest that the manufacturer “*tolerated*, rather than

*intended*, the deviation.” *Id.* Even “an entire industry[’s]” widespread disregard for “certain precautions or improvements” does not necessarily “excuse their omission.” *Id.*

*Grinnell* is also instructive. There, the plaintiffs brought a manufacturing-defect action against a cigarette manufacturer because the cigarettes contained toxic pesticide residue. 951 S.W.2d at 433–34. The manufacturer argued that the plaintiffs’ claims were design-defect claims “masquerading as” manufacturing-defect claims for two reasons: (1) “residue inevitably remain[ed] after fumigation” in all its products and (2) it was undisputed that “pesticide residue [was] incidentally, yet normally” found in tobacco products. *Id.* at 434. In rejecting the defendant’s argument, the Texas Supreme Court noted that “[s]imply because certain precautions or improvements in manufacturing technology . . . are universally disregarded by an entire industry does not excuse their omission.” *Id.*

Similarly, the fact that the heavy metals here are present in virtually all baby-food products does not mean that Hain’s tolerance of ingredients with particularly high heavy-metal levels, like its vitamin pre-mix, was not a manufacturing defect. Viewing the evidence in a light most favorable to the Palmquists and drawing all reasonable inferences in their favor, a genuine issue of material fact exists as to whether Hain’s products contained a

manufacturing defect that caused Ethan’s injury.

### **3. Negligence**

Plaintiffs alleging negligence must show “a duty, a breach of that duty, and damages proximately caused by the breach.” *Kroger Co. v. Elwood*, 197 S.W.3d 793, 794 (Tex. 2006). “While strict liability focuses on the condition of the product, negligence looks at the acts of the manufacturer and determines if it exercised ordinary care in design and production.” *Grinnell*, 951 S.W.2d at 437 (internal quotations omitted).

In their second amended complaint, the Palmquists assert five unique bases for their negligence claim. *See* Dkt. 6 ¶ 41 (including negligent design, production, warning/marketing, and identification/testing arguments). Hain attacks the Palmquists’ negligence claim to the extent it relies on their warning-, design-, or manufacturing-defect arguments in their strict-liability claims. Dkt. 54 at 24–30. In response, the Palmquists merely argue that their “negligent-testing claim” survives summary judgment because Hain did not attack it. Dkt. 69 at 32–33.

In its reply, Hain states that its arguments against the Palmquists’ failure-to-warn claim adequately addressed their negligent-testing claim



because the two claims are “inextricably intertwined.”<sup>6</sup> Dkt. 74 at 23 (citing *Grinnell*, 951 S.W.2d at 437). In *Grinnell*, the Texas Supreme Court said that the plaintiff’s negligent-testing claim “depend[ed] on liability for failure to warn.” *Grinnell*, 951 S.W.2d at 439. But *Grinnell* is distinguishable. There, the court viewed the two types of claims as “inextricably intertwined” because a statute not at issue here, the Public Health Cigarette Smoking Act of 1969, preempted both types of claims. *Id.* Here, Hain does not argue that a federal law preempts the Palmquists’ failure-to-warn and negligent-testing claims such that they are necessarily “intertwined.” Accordingly, the court rejects Hain’s argument that the failure-to-warn and negligent-testing claims are necessarily intertwined.

The Palmquists’ negligent-testing claim survives. Hain did not otherwise argue that it is entitled to summary judgment on the negligent-testing claim. Because the Palmquists abandoned their other negligence claims, the court grants Hain summary judgment on them.

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<sup>6</sup> Hain also argues in its reply that the Palmquists have presented no standard-of-care or breach evidence related to heavy-metal testing in baby-food manufacturing. Dkt. 74 at 14. This argument cannot support Hain’s motion for summary judgment because it first raised the argument in its reply. *Jones v. Cain*, 600 F.3d 527, 541 (5th Cir. 2010) (“Arguments raised for the first time in a reply brief are generally waived.”).

## **B. The Palmquists' Motion for Summary Judgment**

The Palmquists ask for summary judgment on Hain's fourth defense: that Ethan's genetics or pre-existing condition alternatively caused his condition. *See generally* Dkt. 52. The Palmquists first argue that Hain's defense depends on unreliable expert opinions. *Id.* at 4–8. The court previously found that the opinions are admissible and denied the Palmquists' motion to exclude them. Dkt. 99. Thus, as Hain points out, Dkt. 67 at 14, this argument is necessarily insufficient to support the Palmquists' motion for summary judgment.

The Palmquists then argue that the court should dismiss Hain's defense as a matter of law because, even if established, it would not defeat liability. *See* Dkt. 52 at 8 (“[O]nce [the Palmquists] prove that Hain's negligence was sufficient to cause Ethan's injuries . . . it matters not whether his genes were sufficient as well.”). Drawing on analogies from the Second and Third Restatements of Torts, the Palmquists argue that Ethan's alleged genetic abnormalities are, at best, a secondary sufficient cause that is irrelevant once the Palmquists establish that Hain's actions were a substantial factor in causing Ethan's condition. *Id.* at 8–9.

Hain argues, and the court agrees, that the Palmquists' substantial-factor argument is wrong as a matter of law. Dkt. 67 at 15. First, the


Palmquists’ substantial-factor argument misconstrues Hain’s alternative-causation theory as an independent concurrent cause. *See id.* at 11–12; *see, e.g.*, Dkt. 71 at 11. But alternative causation is merely an element for the jury’s consideration “in determining the existence or non-existence of proximate cause.” *E. I. du Pont de Nemours & Co. v. McCain*, 414 F.2d 369, 374 (5th Cir. 1969); *cf. Briley v. Wal-Mart Stores, Inc.*, No. 2:15-CV-439, 2018 WL 276368, at \*6 (S.D. Tex. Jan. 3, 2018) (explaining that although Texas law requires defendants to take victims as they find them, the plaintiff “nonetheless bears the burden of showing that she was injured and that her injuries were proximately caused by [the defendant]’s negligence, and not a pre-existing condition”).

The substantial-factor argument also fails because it requires the court to assume as a matter of law that Hain’s actions caused Ethan’s condition. Dkts. 67 at 16; 52 at 8. The Palmquists have not argued, and the court certainly does not find, that Hain’s actions caused Ethan’s condition as a matter of law. Accordingly, the court will not limit Hain’s ability to argue that Ethan’s genetics or pre-existing conditions alternatively caused his injuries. The court denies the Palmquists’ motion.

\* \* \*

In sum, the court grants Hain's motion, Dkt. 54, on the design-defect claim but denies it as to all other claims. The court denies the Palmquists' motion. Dkt. 52.

Signed on Galveston Island this 31st day of January, 2023

  
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JEFFREY VINCENT BROWN  
UNITED STATES DISTRICT JUDGE